Dkt. 41426-C/JPW/SHS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Ron S. Israeli, et al.

Serial No. : 08/466,381 Group Art Unit: 1645

Filed : June 6, 1995 Examiner: S. Gucker

For : PROSTATE-SPECIFIC MEMBRANE ANTIGEN

1185 Avenue of the Americas
New York, New York 10036
July 2, 2001

Assistant Commissioner for Patents
Washington, D.C. 20231
Box: Sequence

Sir:

STATEMENT IN ACCORDANCE WITH 37 C.F.R. §1.821(f)

In accordance with 37 C.F.R. §1.821(f), I hereby certify that the computer readable form containing the nucleic acid and/or amino acid sequences required by 37 C.F.R. §1.821(e) and submitted in connection with the above-identified application, has the same information as the pages attached hereto as **Exhibit B**, and entitled "Sequence Listing" and contains no new matter.

Respectfully submitted,

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11,14-21,74-76, drawn to a nucleic acid encoding a prostate specific antigen, classified in Class 536, subclass 23.5.

II. Claims 12 and 13, drawn to a method of detecting said antigen with said nucleic acid, classified in Class 435, subclass 6.

III. Claims 23,27,28,29,31 drawn to a ligand, classified in class 530, subclass 350.

IV. Claim 22, drawn to a method of using the ligand to determine if said ligand binds to the antigen, classified in class 435, subclass 7.2.

V. Claims 24 and 25, drawn to the prostate specific antigen, classified in class 530, subclass 350.

VI. Claims 26, drawn to a method of making a ligand, classified in class 530, subclass 412.

VII. Claim 30, drawn to a method of using the ligand for imaging the prostate cancer, classified in class 435, subclass 7.2.

VIII. Claims 32-36, drawn to a antibody, classified in class 530, subclass 387.7.

IX. Claims 37 and 38, drawn to a therapeutic agent comprising said antibody and cytotoxic agent, classified in class 424, subclass 138.1.

X. Claims 39-45, drawn to a method of detection using said antibody and composition comprising said antibody and carrier (or radioisotope), classified in class 435, subclass 7.1.

XI. Claim 46, drawn to a method of purifying said antigen, classified in class 530, subclass 412.

XII. Claims 47 and 48 drawn to a transgenic mammal classified in class 800, subclass 2.

XIII. Claim 49-72,77,84-89 drawn to a method of treatment using the nucleic acid encoding said antigen, classified in claim 514, subclass 44.

XIV. Claims 79-83, drawn to a method of detection using primers of said antigen, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

A. Groups I,II,XII, and XIV drawn to a nucleic acid and Group III,IV,V,VI,VII,VIII,IX,X, and XI, drawn to antigens, antibodies, and ligands are distinct inventions since they are drawn to product with different structure and biological properties.

B. Group I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA can be used for treatment.

C. Group I and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). In the instant case the DNA can be used for detection by mRNA hybridizing to the nucleic acid molecule.

D. Group I and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). In the instant case the DNA can be used for treatment.

E. Group I,II,XIII,XIV drawn to a nucleic acid and Group XII drawn to transgenic animal are distinct inventions since they are drawn to product with different structure and biological properties. Furthermore the method of making the DNA of Group I,II,XIII and XIV does not require the transgenic animal of Group XII.

F. Group II, drawn to a method of detecting said antigen is distinct from Group XIII, and XIV since the methods of each group require different reagents and parameters.

G. Group III and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the ligand can be used for imaging prostate cancer.

H. Group III and Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product

(MPEP §806.05(h)). In the instant case the ligand can be used to determine if the ligand binds to the antigen.

I. Groups VI and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed to make antibodies.

J. Group III,IV,VI,VII drawn to ligand is distinct from Group V,VIII,IX,X,XI,XII,XIII, and XIV drawn to antigens, antibodies, and transgenic animals since they are drawn to product with different structure and biological properties.

K. Groups IV, VI,VII are distinct from each other since the methods require different parameters and reagents.

L. Group V and Xi drawn to an antigen is distinct from Group VIII,IX,X,XII,XIII, and XIV drawn to antibodies, and transgenic animals since they are drawn to products with different structure and biological properties.

M.Groups XI and V are related as process of making and product made. The inventions are distinct if either of both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP §806.05(f)). In the instant case the

protein can be made by recombinant means of Merrifield chemical synthesis.

N. Group VIII and Group IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). In the instant case the antibody can be used for detection.

O. Group VIII and Group X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). In the instant case the antibody can be used for treatment.

P. Groups IX and X are distinct from each other since the methods require different parameters and reagents.

Q. Groups XIII and XIV are distinct from each other since the methods require different parameters and reagents.

3 Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by

their different classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. A telephone call was made to J. White to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR.1.48(b) and by the fee required under 37 CFR 1.17(h).

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony C. Caputa, Ph.D whose telephone number is (703) 308-0196.

Caputa/sg
January 29, 1997

ANTHONY C. CAPUTA
PRIMARY EXAMINER
GROUP 1800